

# **SOCIETY for RESEARCH on NICOTINE and TOBACCO**

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June 16, 2000

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## **STAFF**

Sarah E. Evans  
Executive Director

Jane Henney, M.D.  
Commissioner  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Re: Regulation of Eclipse

Dear Dr. Henney,

The Society for Research on Nicotine and Tobacco (SRNT) urges The Food and Drug Administration to review the health claims RJ Reynolds is making for their Eclipse product. We believe there is insufficient and contrary scientific results to support these claims and thus FDA should institute some form of regulatory procedures over Eclipse.

Our society consists of 600+ of the leading scientists in tobacco and nicotine research in the US and 33 other countries; thus, SRNT is the largest repository of scientific information in the world. One of SRNT's major missions is to provide scientific data and advise to policy makers.

Our reasons for urging FDA to review Eclipse health claims are as follows:

- Smokers do believe and often overestimate health claims made by the tobacco industry. For example, a recent NCI/ Presidential Commission report<sup>1</sup> (and other studies<sup>2</sup>) concluded that most smokers believe low tar/nicotine cigarettes are safer even though these products make only vague implicit health claims in their advertising. The NCI report (and other reports<sup>3</sup>) also conclude the health benefits of low tar/nicotine cigarettes are either non-existent or very small. Finally, recent scientific<sup>2,4</sup> and industry documents<sup>5</sup> suggest the marketing of low tar/low nicotine cigarettes has undermined many smokers intentions to stop smoking.
- Although there are data that Eclipse delivers fewer carcinogens than regular cigarettes,<sup>6-10</sup> there are problems with these data. For example, machine-testing data<sup>6-8</sup> must be interpreted cautiously because experience with low tar/nicotine cigarettes clearly shows that people do not smoke like machines do.<sup>3</sup> To our knowledge, there are only two published studies of carcinogen exposure in

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humans using Eclipse.<sup>9,10</sup> These studies used small samples, short durations of exposure and were conducted by the tobacco industry.

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Sarah L. Evans  
Executive Director

- Both an independent study<sup>11</sup> and an industry study<sup>12</sup> found that use of Eclipse increased carbon monoxide (CO) levels compared to smoking traditional cigarettes. This is important as increased CO is linked to cardiovascular disease<sup>13</sup> and smokers are more likely to die of tobacco-induced cardiovascular diseases than of tobacco-induced cancers<sup>14</sup>.
- Eclipse exposes smokers to inhalation of fiber glass particles;<sup>15</sup> thus, Eclipse may add a new risk of cancer and lung diseases.
- It is unclear how Eclipse will be used. The only study of the use pattern of Eclipse did not present Eclipse in the manner that RJR is pursuing.<sup>11</sup> Smokers might substitute Eclipse for cigarettes. On the other hand, they might use Eclipse solely to avoid smoking restrictions and just add Eclipse use to their ongoing daily consumption of cigarettes. If the later is true, Eclipse could actually increase risk.
- The availability of Eclipse along with claims of it being a safer cigarette might increase initiation of smoking or would undermine motivation for stopping smoking. Although an initial study suggests that Eclipse does not undermine motivation to quit,<sup>11</sup> this study lacked an adequate control group to clearly answer the question.

In summary, SRNT believes there are many unanswered questions about the validity of the health claims made by Eclipse.<sup>16,17</sup> In fact, we believe the availability of Eclipse could result in a net worsening of public health due to increased CO levels, glass inhalation, higher rates of initiation of smoking, or lower rates of cessation of smoking. In addition, other cigarette substitutes (e.g. Accord) and "safer tobacco" products (e.g. Star Tobacco) are likely to make health claims in the not too distant future. Thus, SRNT urges the FDA to institute regulatory procedures to require sufficient study of Eclipse so that the policy mistakes that were made with low-tar/low-nicotine cigarettes are not repeated with Eclipse and other smoking products making health claims.

Sincerely,

  
John R. Hughes, M.D.  
Chair, Policy Committee  
SRNT

cc: Geoff Mumford  
Judy Wilkenfeld  
SRNT Office  
Bill Corrigan

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